

Inspection Checklist for Toxin Laboratories (7 CFR 331; 9 CFR 121; 42 CFR 73; BMBL 5 <sup>th</sup> Edition; 29 CFR:1910.1450)					
Inspection Date:					
Entity Name:					
Responsible Official:					
SAP Inspector(s):					
Principal Investigator (P.I.):					
Laboratory Location - Street Address:					
Building:					
Room number(s):					
Agent(s)/Toxin(s):					
<b>When Information is entered in this form, the form is to be considered "Sensitive Select Agent Information."</b>					
Reference	Statement	Response			Comments
		Yes	No	N/A	
CFR: Section 12 (c)(2)	In developing a biosafety plan, an individual or entity should consider: The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR parts 1910.1200 and 1910.1450.				
CFR: Section 12 (d)	The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				
CFR: Section 13 (a)	An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator.				
CFR: Section 13 (b)(2)	<i>Restricted experiments:</i> Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.				
BMBL: Appendix I Training and Laboratory Planning	Each laboratory worker must be trained in the theory and practice of the toxins to be used, with special emphasis on the nature of the practical hazards associated with laboratory operations. This includes how to handle transfers of liquids containing toxin, where to place waste solutions and contaminated materials or equipment, and how to decontaminate work areas after routine operations, as well as after accidental spills. The worker must be reliable and sufficiently adept at all required manipulations before being provided with toxin.				
BMBL: Appendix I Training and Laboratory Planning	For complex operations, it is recommended that new workers undergo supervised practice runs in which the exact laboratory procedures to be undertaken are rehearsed without active toxin.				

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<b>BMBL: Appendix I</b> <i>Training and Laboratory Planning</i>	If toxins and infectious agents are used together, then both must be considered when containment equipment is selected and safety procedures are developed. Likewise, animal safety practices must be considered for toxin work involving animals.				
<b>BMBL: Appendix I</b> <i>Training and Laboratory Planning</i>	Each laboratory that uses toxins should develop a specific chemical hygiene plan. The National Research Council has provided a review of prudent laboratory practices when handling toxic and highly toxic chemicals, including the development of chemical hygiene plans and guidelines for compliance with regulations governing occupational safety and health, hazard communication, and environmental protection.				
<b>BMBL: Appendix I</b> <i>Training and Laboratory Planning</i>	An inventory control system should be in place to account for toxin use and disposition.				
<b>BMBL: Appendix I</b> <i>Training and Laboratory Planning</i>	If toxins are stored in the laboratory, containers should be sealed, labeled, and secured to ensure restricted access; refrigerators and other storage containers should be clearly labeled and provide contact information for trained, responsible laboratory staff.				
<b>BMBL: Appendix I</b> <i>Training and Laboratory Planning</i>	Laboratory work with toxins should be done only in designated rooms with controlled access and at pre-determined bench areas.				
<b>BMBL: Appendix I</b> <i>Training and Laboratory Planning</i>	When toxins are in use, the room should be clearly posted: "Toxins in Use—Authorized Personnel Only."				
<b>BMBL: Appendix I</b> <i>Training and Laboratory Planning</i>	Unrelated and nonessential work should be restricted from areas where stock solutions of toxin or organisms producing toxin are used.				
<b>BMBL: Appendix I</b> <i>Training and Laboratory Planning</i>	Visitors or other untrained personnel granted laboratory access must be monitored and protected from inadvertently handling laboratory equipment used to manipulate the toxin or organism.				

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<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	Routine operations with dilute toxin solutions are conducted under BSL-2 conditions with the aid of personal protective equipment and a well-maintained BSC or comparable engineering controls. Engineering controls should be selected according to the risk assessment for each specific toxin operation.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	A certified BSC or chemical fume hood will suffice for routine operations with most protein toxins.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	Low molecular weight toxin solutions, or work involving volatile chemicals or radionucleotides combined with toxin solutions, may require the use of a charcoal-based hood filter in addition to HEPA filtration.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	All work with toxins should be conducted within the operationally effective zone of the hood or BSC, and each user should verify the inward airflow before initiating work.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	When using an open-fronted fume hood or BSC, workers should wear suitable laboratory PPE to protect the hands and arms, such as laboratory coats, smocks, or coveralls and disposable gloves.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	When working with toxins that pose direct percutaneous hazards, special care must be taken to select gloves that are impervious to the toxin and the diluents or solvents employed.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	When conducting liquid transfers and other operations that pose a potential splash or droplet hazard in an open-fronted hood or BSC, safety glasses and disposable facemask, or a face shield, should be worn.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	Toxin should be removed from the hood or BSC only after the exterior of the closed primary container has been decontaminated and placed in a clean secondary container.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	Toxin solutions, especially concentrated stock solutions, should be transported in leak/spill-proof secondary containers.				

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<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	The interior of the hood or BSC should be decontaminated periodically, for example, at the end of a series of related experiments.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	Until thoroughly decontaminated, the hood or BSC should be posted to indicate that toxins remain in use, and access should remain restricted.				
<b>BMBL: Appendix I</b> <i>Safety Equipment and Containment</i>	Selected operations with toxins may require modified BSL-3 practices and procedures. The determination to use BSL-3 is made in consultation with available safety staff and is based upon a risk assessment that considers the variables of each specific laboratory operation, especially the toxin under study, the physical state of the toxin (solution or dry form), the total amount of toxin used relative to the estimated human lethal dose, the volume of the material manipulated, the methodology, and any human or equipment performance limitations.				
<b>BMBL: Appendix I</b> <i>Inadvertent Toxin Aerosols</i>	Emphasis must be placed on evaluating and modifying experimental procedures to eliminate the possibility of inadvertent generation of toxin aerosols.				
<b>BMBL: Appendix I</b> <i>Inadvertent Toxin Aerosols</i>	Pressurized tubes or other containers holding toxins should be opened in a BSC, chemical fume hood, or other ventilated enclosure.				
<b>BMBL: Appendix I</b> <i>Inadvertent Toxin Aerosols</i>	Operations that expose toxin solutions to vacuum or pressure, for example sterilization of toxin solutions by membrane filtration, should always be handled in this manner, and the operator should also use appropriate respiratory protection.				
<b>BMBL: Appendix I</b> <i>Inadvertent Toxin Aerosols</i>	If vacuum lines are used with toxin, they should be protected with a HEPA filter to prevent entry of toxins into the line.				
<b>BMBL: Appendix I</b> <i>Inadvertent Toxin Aerosols</i>	Centrifugation of cultures or materials potentially containing toxins should only be performed using sealed, thick-walled tubes in safety centrifuge cups or sealed rotors. The outside surfaces of containers and rotors should be routinely cleaned before each use to prevent contamination that may generate an aerosol. After centrifugation, the entire rotor assembly is taken from the centrifuge to a BSC to open it and remove its tubes.				
<b>BMBL: Appendix I</b> <i>Mechanical Injuries</i>	Only workers trained and experienced in handling animals should be permitted to conduct operations involving injection of toxin solutions using hollow-bore needles.				

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<b>BMBL: Appendix I</b> <i>Mechanical Injuries</i>	Discarded needles/syringes and other sharps should be placed directly into properly labeled, puncture-resistant sharps containers, and decontaminated as soon as is practical.				
<b>BMBL: Appendix I</b> <i>Mechanical Injuries</i>	Glassware should be replaced with plastic for handling toxin solutions wherever practical to minimize the risk of cuts or abrasions from contaminated surfaces.				
<b>BMBL: Appendix I</b> <i>Mechanical Injuries</i>	Thinwalled glass equipment should be completely avoided. Glass Pasteur pipettes are particularly dangerous for transferring toxin solutions and should be replaced with disposable plastic pipettes. Glass chromatography columns under pressure must be enclosed within a plastic water jacket or other secondary container.				
<b>BMBL: Appendix I</b> <i>Additional Precautions</i>	Experiments should be planned to eliminate or minimize work with dry toxin (e.g. freeze-dried preparations). Unavoidable operations with dry toxin should only be undertaken with appropriate respiratory protection and engineering controls.				
<b>BMBL: Appendix I</b> <i>Additional Precautions</i>	Dry toxin can be manipulated using a Class III BSC, or with the use of secondary containment such as a disposable glove bag or glove box within a hood or Class II BSC.				
<b>BMBL: Appendix I</b> <i>Additional Precautions</i>	"Static-free" disposable gloves should be worn when working with dry forms of toxins that are subject to spread by electrostatic dispersal.				
<b>BMBL: Appendix I</b> <i>Additional Precautions</i>	In specialized laboratories, the intentional, controlled generation of aerosols from toxin solutions may be undertaken to test antidotes or vaccines in experimental animals. These are extremely hazardous operations that should only be conducted after extensive validation of equipment and personnel, using non-toxic simulants.				
<b>BMBL: Appendix I</b> <i>Additional Precautions</i>	Aerosol exposure of animals should be done in a certified Class III BSC or hoodline.				
<b>BMBL: Appendix I</b> <i>Additional Precautions</i>	While removing exposed animals from the hoodline, and for required animal handling during the first 24 h after exposure, workers should take additional precautions, including wearing protective clothing (e.g., disposable Tyvek suit) and appropriate respiratory protection.				
<b>BMBL: Appendix I</b> <i>Additional Precautions</i>	To minimize the risk of dry toxin generating a secondary aerosol, areas of animal skin or fur exposed to aerosols should be gently wiped with a damp cloth containing water or buffered cleaning solution before the animals are returned to holding areas.				
<b>BMBL: Appendix I</b> <i>Additional Precautions</i>	For high-risk operations involving dry forms of toxins, intentional aerosol formation, or the use of hollow-bore needles in conjunction with amounts of toxin estimated to be lethal for humans, consideration should be given to requiring the presence of at least two knowledgeable individuals at all times in the laboratory.				

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<b>BMBL: Appendix I Decontamination and Spills</b>	Depending upon the toxin, contaminated materials and toxin waste solutions can be inactivated by incineration or extensive autoclaving, or by soaking in suitable decontamination solutions.				
<b>BMBL: Appendix I Decontamination and Spills</b>	All disposable material used for toxin work should be placed in secondary containers, autoclaved and disposed of as toxic waste.				
<b>BMBL: Appendix I Decontamination and Spills</b>	Contaminated or potentially contaminated protective clothing and equipment should be decontaminated using suitable chemical methods or autoclaving before removal from the laboratory for disposal, cleaning or repair. If decontamination is impracticable, materials should be disposed of as toxic waste.				
<b>BMBL: Appendix I Decontamination and Spills</b>	In the event of a spill, avoid splashes or generating aerosols during cleanup by covering the spill with paper towels or other disposable, absorbent material. Apply an appropriate decontamination solution to the spill, beginning at the perimeter and working towards the center, and allow sufficient contact time to completely inactivate the toxin.				
<b>29 CFR:1910.1450 (e)(1)</b>	Where hazardous chemicals as defined by this standard are used in the workplace, the employer shall develop and carry out the provisions of a written Chemical Hygiene Plan which is:				
<b>29 CFR:1910.1450 (e)(1)(i)</b>	Capable of protecting employees from health hazards associated with hazardous chemicals in that laboratory.				
<b>29 CFR:1910.1450 (e)(1)(ii)</b>	Capable of keeping exposures below the permissible exposure limits.				
<b>29 CFR:1910.1450 (e)(2)</b>	The Chemical Hygiene Plan shall be readily available to employees, employee representatives and, upon request, to the Assistant Secretary.				
<b>29 CFR:1910.1450 (e)(3)</b>	The Chemical Hygiene Plan shall include each of the following elements and shall indicate specific measures that the employer will take to ensure laboratory employee protection:				
<b>29 CFR:1910.1450 (e)(3)(i)</b>	Standard Operating Procedures relevant to safety and health considerations to be followed when laboratory work involves the use of hazardous chemicals.				
<b>29 CFR:1910.1450 (e)(3)(ii)</b>	Criteria that the employer will use to determine and implement control measures to reduce employee exposure to hazardous chemicals including engineering controls, the use of personal protective equipment and hygiene practices; particular attention shall be given to the selection of control measures for chemicals that are known to be extremely hazardous.				
<b>29 CFR:1910.1450 (e)(3)(iii)</b>	A requirement that fume hoods and other protective equipment are functioning properly and specific measures that shall be taken to ensure proper and adequate performance of such equipment.				

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<b>29 CFR:</b> 1910.1450 (e)(3)(iv)	Provisions for employee information and training as prescribed in 29 CFR 1910.1450 (f).				
<b>29 CFR:</b> 1910.1450 (e)(3)(v)	The circumstances under which a particular laboratory operation, procedure or activity shall require prior approval from the employer or the employer's designee before implementation.				
<b>29 CFR:</b> 1910.1450 (e)(3)(vi)	Provisions for medical consultation and medical examinations in accordance with 29 CFR 1910.1450 (g).				
<b>29 CFR:</b> 1910.1450 (e)(3)(vii)	Designation of personnel responsible for implementation of the Chemical Hygiene Plan including the assignment of a Chemical Hygiene Officer and, if appropriate, establishment of a Chemical Hygiene Committee.				
<b>29 CFR:</b> 1910.1450 (e)(3)(viii)	Provisions for additional employee protection for work with particularly hazardous substances. These include "select carcinogens," reproductive toxins and substances which have a high degree of acute toxicity. Specific considerations shall be given to the following provisions which shall be included where appropriate:				
<b>29 CFR:</b> 1910.1450 (e)(3)(viii)(A)	Establishment of a designated area.				
<b>29 CFR:</b> 1910.1450 (e)(3)(viii)(B)	Use of containment devices such as fume hoods or glove boxes.				
<b>29 CFR:</b> 1910.1450 (e)(3)(viii)(C)	Procedures for safe removal of contaminated waste.				
<b>29 CFR:</b> 1910.1450 (e)(3)(viii)(D)	Method of decontamination used should be effective against the toxin used in the laboratory.				
<b>29 CFR:</b> 1910.1450 (e)(4)	The employer shall review and evaluate the effectiveness of the Chemical Hygiene Plan at least annually and update it as necessary.				
<b>29 CFR:</b> 1910.1450 (f)(1)	The employer shall provide employees with information and training to ensure that they are apprised of the hazards of chemicals present in their work area.				
<b>29 CFR:</b> 1910.1450 (f)(2)	Such information shall be provided at the time of an employee's initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. The frequency of refresher information and training shall be determined by the employer.				
<b>29 CFR:</b> 1910.1450 (f)(3)	Employees shall be informed of:				
<b>29 CFR:</b> 1910.1450 (f)(3)(i)	The contents of this standard and its appendices which shall be made available to employees.				
<b>29 CFR:</b> 1910.1450 (f)(3)(ii)	The location and availability of the employer's Chemical Hygiene Plan.				

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<b>29 CFR:</b> 1910.1450 (f)(3)(iii)	The permissible exposure limits for OSHA regulated substances or recommended exposure limits for other hazardous chemicals where there is no applicable OSHA standard.				
<b>29 CFR:</b> 1910.1450 (f)(3)(iv)	Signs and symptoms associated with exposures to hazardous chemicals used in the laboratory.				
<b>29 CFR:</b> 1910.1450 (f)(3)(v)	The location and availability of known reference material on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, Material Safety Data Sheets received from the chemical supplier.				
<b>29 CFR:</b> 1910.1450 (f)(4)(i)	Employee training shall include:				
<b>29 CFR:</b> 1910.1450 (f)(4)(i)(A)	Methods and observations that may be used to detect the presence or release of a hazardous chemical (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.).				
<b>29 CFR:</b> 1910.1450 (f)(4)(i)(B)	The physical and health hazards of chemicals in the work area.				
<b>29 CFR:</b> 1910.1450 (f)(4)(i)(C)	The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.				
<b>29 CFR:</b> 1910.1450 (f)(4)(ii)	The employee shall be trained on the applicable details of the employer's written Chemical Hygiene Plan.				
<b>29 CFR:</b> 1910.1450 (g)(1)	The employer shall provide all employees who work with hazardous chemicals an opportunity to receive medical attention, including any follow-up examinations which the examining physician determines to be necessary, under the following circumstances:				
<b>29 CFR:</b> 1910.1450 (g)(1)(i)	Whenever an employee develops signs or symptoms associated with a hazardous chemical to which the employee may have been exposed in the laboratory, the employee shall be provided an opportunity to receive an appropriate medical examination.				
<b>29 CFR:</b> 1910.1450 (g)(1)(ii)	Where exposure monitoring reveals an exposure level routinely above the action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring and medical surveillance requirements, medical surveillance shall be established for the affected employee as prescribed by the particular standard.				
<b>29 CFR:</b> 1910.1450 (g)(1)(iii)	Whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure, the affected employee shall be provided an opportunity for a medical consultation. Such consultation shall be for the purpose of determining the need for a medical examination.				



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<b>29 CFR:</b> 1910.1450 (g)(2)	All medical examinations and consultations shall be performed by or under the direct supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.				
<b>29 CFR:</b> 1910.1450 (g)(3)	The employer shall provide the following information to the physician:				
<b>29 CFR:</b> 1910.1450 (g)(3)(i)	The identity of the hazardous chemical(s) to which the employee may have been exposed;				
<b>29 CFR:</b> 1910.1450 (g)(3)(ii)	A description of the conditions under which the exposure occurred including quantitative exposure data, if available; and				
<b>29 CFR:</b> 1910.1450 (g)(3)(iii)	A description of the signs and symptoms of exposure that the employee is experiencing, if any.				
<b>29 CFR:</b> 1910.1450 (g)(4)(i)	For examination or consultation required under this standard, the employer shall obtain a written opinion from the examining physician which shall include the following:				
<b>29 CFR:</b> 1910.1450 (g)(4)(i)(A)	Any recommendation for further medical follow-up;				
<b>29 CFR:</b> 1910.1450 (g)(4)(i)(B)	The results of the medical examination and any associated tests;				
<b>29 CFR:</b> 1910.1450 (g)(4)(i)(C)	Any medical condition which may be revealed in the course of the examination which may place the employee at increased risk as a result of exposure to a hazardous chemical found in the workplace; and				
<b>29 CFR:</b> 1910.1450 (g)(4)(i)(D)	A statement that the employee has been informed by the physician of the results of the consultation or medical examination and any medical condition that may require further examination or treatment.				
<b>29 CFR:</b> 910.1450 (g)(4)(ii)	The written opinion shall not reveal specific findings of diagnoses unrelated to occupational exposure.				
<b>29 CFR:</b> 1910.1450 (h)(1)	With respect to labels and Material Safety Data Sheets (MSDS):				
<b>29 CFR:</b> 1910.1450 (h)(1)(i)	Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced.				
<b>29 CFR:</b> 1910.1450 (h)(1)(ii)	Employers shall maintain any Material Safety Data Sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees.				
<b>29 CFR:</b> 1910.1450 (h)(2)	The following provisions shall apply to chemical substances developed in the laboratory:				

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<b>29 CFR:1910.1450</b> (h)(2)(i)	If the composition of the chemical substance which is produced exclusively for the laboratory's use is known, the employer shall determine if it is a hazardous chemical as defined in paragraph (b) of this section. If the chemical is determined to be hazardous, the employer shall provide appropriate training as required under paragraph (f) of this section.				
<b>29 CFR:1910.1450</b> (h)(2)(ii)	If the chemical produced is a byproduct whose composition is not known, the employer shall assume that the substance is hazardous and shall implement paragraph (e) of this section.				
<b>29 CFR:1910.1450</b> (h)(2)(iii)	If the chemical substance is produced for another user outside of the laboratory, the employer shall comply with the Hazard Communication Standard (29 CFR 1910.1200) including the requirements for preparation of material safety data sheets and labeling.				
<b>29 CFR:1910.1450</b> (i)	Where the use of respirators is necessary to maintain exposure below PEL, the employer shall provide, at no cost to the employee, the proper respirator equipment. Respirators shall be selected and used in accordance with the requirements of 29 CFR 1910.134.				
<b>29 CFR:1910.1450</b> (j)(1)	The employer shall establish and maintain for each employee an accurate record of any measurements taken to monitor employee exposures and any medical consultation and examinations including tests or written opinions required by this standard.				
<b>29 CFR:1910.1450</b> (j)(2)	The employer shall assure that such records are kept, transferred, and made available in accordance with 29 CFR 1910.1020.				

[illegible]